ALFRED B. ENGELBERG
1050 NORTH LAKE WAY
PALM BEACH, FLORIDA 33480
Phone: (561) 848-7089• Fax: (561) 848-4383

October 26, 2002

Dockets Management Branch(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Regulations Affecting 30 Month Stay Provision of Hatch-Waxman
Docket No. 02N-0417

Dear Sir or Madam:

I was patent counsel to the Generic Pharmaceutical Industry Association (GPIA) in 1984 and for many years thereafter and was intimately involved in drafting the original 30 month stay and 180-day generic exclusivity provisions. I have retired and no longer represent GPIA or its successor GPhA nor any other association corporation or individual with an economic interest in the subject matter. The attached memorandum commenting on the proposed new regulations is being submitted in the public interest.

Sincerely,

Alfred B. Engelberg

~~98D-0484~~
02N-0417

~~C15~~
C2

ALFRED B. ENGELBERG
1050 NORTH LAKE WAY
PALM BEACH, FLORIDA 33480
Phone: (561) 848-7089• Fax: (561) 848-4383

October 25, 2002

The Bush/FDA Proposal on the Hatch-Waxman 30 Month Rule--It Doesn't Work

This memo summarizes the nature of the proposal; why the proposal does not accomplish the purpose of eliminating the abuse of the 30 month rule and why the proposed regulation is unlawful. It also suggests a regulatory change that would be both effective and lawful.

The Proposed New Regulation

Under current law, when a party files an application (ANDA) seeking approval for a generic copy of a previously approved new drug (NDA), the applicant is required to file a patent certification as to each patent the NDA holder has identified as covering the new drug. The identified patents are published in the FDA Orange Book. The certification can state that the applicant is seeking approval after a listed patent expires ("a paragraph III certification)" or it may ask for immediate approval on the ground that a listed patent is invalid or not infringed ("a paragraph IV certification"). If a paragraph IV certification is made, the applicant must give written notice to the patent owner. If the patent owner files suit within 45 days after receiving the notice, the FDA is prohibited from approving the ANDA for 30 months unless there is an earlier court decision holding the patent to be invalid or non-infringed. If new patents are issued to the NDA holder after the NDA is approved they must be listed in the Orange Book within 30 days. Current regulations require that if a new patent is belatedly listed, any pending generic application must be amended to contain a patent certification with respect to each newly listed patent. If the amended certification is a paragraph IV certification challenging the belatedly-listed patent, a new notice, a new litigation and a new 30 month stay are possible.

The Bush regulatory proposal states that when a pending ANDA is amended for the purpose of asserting a paragraph IV certification against a belatedly-listed patent, a notice of the patent challenge does not have to be served on the patent holder **but only if** a prior paragraph IV patent challenge notice had been served in the same ANDA application against an earlier listed patent. Since the 30 month stay is triggered by the notice, there could only be one 30 month stay of any generic drug application.

The Proposed Regulation Does Not Achieve Its Intended Purpose

The public is wrongfully deprived of the cost savings that flow from generic drug competition when a non-meritorious patent is used to delay legitimate competition. In non-drug patent cases, the mere assertion of a patent would not eliminate competition because a party challenging a patent can make, use and sell its product while litigation is pending unless a court enters a preliminary injunction. The 30 month stay provides an automatic injunction by virtue of the mere assertion of a patent irrespective of its merit. Therefore, the abuse of the 30 month rule most often occurs when a non-meritorious patent is belatedly listed in the Orange Book shortly

before basic patents covering the same product are about to expire. These patents usually cover formulations, metabolites, different crystalline forms ("polymorphs") and other subject matter as to which there is either no reasonable possibility of infringement or the patent is invalid because the claimed subject matter is not sufficiently different from that claimed in earlier patents.

The Bush/FDA proposal merely prohibits successive 30 months stays against the same ANDA. This would not prevent the belated assertion of non-meritorious patent claims in most cases. For example:

1. If the generic applicant had never filed a patent challenge against any of the basic patents originally listed in the Orange Book, any non-meritorious, belatedly listed patent would still get an automatic 30 month stay and delay legitimate competition. Patent challenges against basic patents are relatively rare. The recent increase in patent challenges has largely been due to an increase in the number of belatedly-listed patents.

2. The 180-day generic exclusivity rule prohibits the FDA from approving any generic application until 180-days after the first ANDA applicant to file a patent challenge against a particular patent has either (i) entered the market or (ii) obtained a favorable court decision. Therefore, unless the first ANDA applicant to file a patent challenge against a belatedly-listed patent has previously filed a challenge against an earlier listed patent on the same drug, all ANDAs will be held hostage to that 30 month stay irrespective of whether any of those applications had been subject to a prior 30 month stay as a result of an earlier patent challenge. For this reason, the proposed regulation will only rarely and randomly operate to prevent unwarranted delays in competition.

Clearly, the obvious solution to the problem caused by the belated listing of non-meritorious patents is to directly deprive those patents of eligibility for the 30 month stay. Such a limitation is completely consistent with the original intent of the Hatch-Waxman Act. The Act was concerned with providing added protections such as patent term extensions and the 30 month stay for patents that had issued before a new drug was approved. Because those patents had been deprived of commercial monopoly life as a result of delays in the regulatory approval process, Congress enacted special provisions to prevent additional shortening of the monopoly. A patent granted long after a new drug is approved has its full economic term and is not entitled to any special protections such as an automatic 30 month injunction.

The Proposed Regulation is Unlawful

Any regulatory change in the enforcement of the 30 month rule must be consistent with the Hatch-Waxman Act or it will be struck down by the courts as an unlawful regulation. The Bush/FDA proposal conflicts with the basic intent of Hatch-Waxman that will not survive judicial scrutiny.

The Hatch-Waxman Act states: "If an application {ANDA} is amended to include a certification described in paragraph (2) (A) (IV) {a paragraph IV certification} the notice required by subparagraph (b) shall be given when the amended application is submitted." The FDA's explanation of its proposed new regulation argues that an application that previously "included" a paragraph IV patent challenge is not being amended to "include" such a certification because it already "includes"one. This is pure semantic nonsense. The Hatch-Waxman Act clearly requires

a separate certification with respect to "**each**" listed patent. See 21USC 355 (j) (2) (A). Therefore, FDA's attempt to argue that a prior paragraph IV certification notice with respect to one patent eliminates the requirement for a separate notice with respect to a separate paragraph IV challenge against a different patent makes no sense. The entire purpose of the patent certification provisions of Hatch-Waxman was to expedite the resolution of patent controversies so that they could be decided during the same period of time that an ANDA was under technical review by the FDA. Eliminating the requirement for notice following the filing of a paragraph IV patent challenge totally eliminates the possibility of expedited resolution and is inconsistent with the clear intent of the statute.

A More Suitable Regulatory Solution Is Available

Ironically, the Hatch-Waxman Act does not explicitly require an applicant for an ANDA to amend the patent certification that is required to be filed with the initial application. That concept was established by FDA regulations. It is arguably improper and inequitable since the decision as to whether (and when) to invest in the filing of an ANDA is directly influenced by the expiration dates of the patents listed in the Orange Book at the time the investment decision is made. Elimination of the requirement to file an amended certification for patents listed after the initial certification is filed would eliminate the possibility of 30 month stays with respect to belatedly-listed patent. The FDA has put itself in a logically impossible position by insisting that amended certifications are required with respect to late-listed patents but notice of those certifications may not be required.

As it turns out, under existing law, no ANDA can be filed for a new drug until at least four years after the NDA is approved. In addition, any patent claiming some aspect of a new drug would be invalid, as a matter of patent law, unless the application for that patent was filed within 12 months of the NDA approval date. The average time between the filing of a patent application and the issuance of a patent is about 3 years. Therefore, all patents that could reasonably claim some aspect of the new drug will normally be listed in the Orange Book long before any ANDA's are filed. Indeed, in the absence of a patent challenge against a basic patent, the first ANDA for a new drug is usually not filed for 10 years or more, since most applicants wait until 3-4 years before the basic patents on a new drug expire before seeking approval for a generic copy. Given these circumstances there are powerful legal arguments, in addition to the equitable argument, for not requiring ANDA applicant's to file amended patent certifications with respect to patents that are first listed in the Orange Book long after an ANDA has been filed. Patent owners would still have the full right of enforcement of those belated patents, including the right to seek a preliminary injunction from a court. But such patents could no longer delay generic approvals simply by listing them in the Orange Book.